

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

March 9, 2010
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

CALL TO ORDER: The meeting was called to order at 9AM.

PRESIDING: Jennifer H. Edwards, Chairman

MEMBERS PRESENT: Gill B. Abernathy
John O. Beckner
Willie Brown
Gerard Dabney
Bobby Ison
David C. Kozera
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Sharon Davenport, Administrative Assistant
Eusebia Joyner, Discipline Program Specialist

QUORUM: With 10 members present, a quorum was established.

APPROVAL OF AGENDA: There were three modifications to the agenda. Sandra Whitley Ryals, Director, DHP, was not able to be present to give the DHP report due to a family emergency. A handout was provided to the Board with information on the second quarter 2010 performance measures. Mr. Ison requested that an additional item be added to the agenda for discussion as to how the Board can assist PICs with compliance. Additionally, Ms. Reiniers-Day stated that a possible summary suspension would be presented. With these three changes, the agenda was approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for December 16, 2009; January 26, 2010; February 23, 2010; February 22, 2010; and February 24, 2010.

Motion: **The Board voted unanimously to approve the minutes as presented with one minor change to the minutes of January 26, 2010, changing the name of the second to a motion from Mr. Yi to Mr. Kozera. (motion by Dabney, second by Brown)**

PUBLIC COMMENTS: There were no public comments offered at this time.

LEGISLATION UPDATE: Ms. Yeatts provided a summary of legislation from the 2010 General Assembly session that might be of possible interest to the Board.

REGULATIONS: Ms. Yeatts provided an update on existing regulatory processes.

- Adoption of final regulations on drug donation programs: Ms. Yeatts stated that the Board had received no comments during the comment period on the proposed regulations. She stated that there were no changes in final regulations from existing emergency regulations. The Board discussed whether the requirement for a signed donor form by nursing home patients was acting as a deterrent to pharmacies other than the provider pharmacy from registering as a donation site for a long term care facility. Staff provided information that the current regulations were formulated by an ad hoc committee that included long term care pharmacy representation, and that there were no issues with the donor form. Ms. Russell stated that the Board currently had two pharmacies registered as donation sites. Ms. Russell gave the opinion that the real barrier to pharmacies wanting to participate in these programs is that there is a financial disincentive to doing so. It is an additional burden in terms of workload, storage space for these drugs, and recordkeeping systems for no income. Ms. Abernathy expressed concern that, for the reasons just mentioned, the Board should make the process as simple as possible and not require anything non-essential such as possibly the donor form from nursing home patients. Ms. Yeatts again reiterated that the original committee drafting the regulations considered that the donor form requirement was necessary in this example because a pharmacy other than the provider pharmacy did not have the patient records and dispensing records that the provider pharmacy would have. She also reminded the Board that any substantive change now would require resubmitting the regulations again for public comment and further delaying the implementation of permanent regulations. As it is, the emergency regulations expire April 9, 2010 and a six-month extension is being requested to have permanent regulations in place. Any further delay in this process will mean a gap in which the emergency regulations expire, and any programs that may be ongoing will need to cease until permanent regulations become effective.

Motion: **The Board voted unanimously to adopt as final regulations the proposed regulations as published. (motion by Yi, second by Kozera)**

Motion: **The Board voted unanimously to have staff communicate with associations representing nursing homes to determine if there are barriers in Board regulations that are preventing more participation in drug donation programs. (motion by Abernathy, second by Ross)**

- Adoption of a fast-track regulation on removing the requirement for delivery signature by a nurse for drugs placed in ADDs in hospitals:
- The Board reviewed draft regulations eliminating the requirement for a nurse to sign for delivery of drugs placed into an automated dispensing device (ADD) in a hospital. This proposal was a response to a petition for rulemaking, for which the Board received a number of responses in support of eliminating the requirement primarily for the reasons that it took the nurse away from more important patient care duties without providing any additional accountability for the process since it was not required that the nurse witness the drugs being stocked in the ADD. The Board received no additional comments during the NOIRA process, and it is not anticipated that there is any opposition to this action.

Motion: **The Board voted unanimously to adopt proposed regulation as presented to eliminate the requirement for a nurse's signature on the delivery record of drugs stocked in an ADD in a hospital. (motion by Ison, second by Beckner) Attachment 1.**

- Adoption of emergency regulations to implement HB150, effective date March 4, 2010.
- House Bill 150 of the 2010 General Assembly provided authority for the Community Services Boards (CSBs) who hold controlled substances registrations as alternate delivery sites, to retain medications for certain patients with consent, and assist those patients with repackaging for self-administration. The bill also provides for crisis stabilization units in CSBs to have certain Schedule VI drugs stocked for administration by a nurse pursuant to an order of a prescriber, but in the absence of a prescriber. The bill contained an emergency enactment clause as well as a requirement for the Board of Pharmacy to adopt emergency regulations to implement the provisions of the bill. The regulations include provisions related to the retention and repackaging of medications by the CSBs, the training for any unlicensed persons assisting with repackaging at the CSBs, and storage and record requirements for the crisis stabilization units.

An ad hoc committee consisting of Board members and representatives of the CSBs met on February 23, 2010 and developed draft regulations for consideration by the Board. The Board reviewed the draft regulations and made some minor technical revisions. Prevention and reporting of errors was added

to the list of items to be included in an approved training program.

Motion:

The Board voted unanimously to adopt emergency regulations to implement HB150, as recommended by the ad hoc committee and amended by the Board. (motion by Stredler, second by Brown) Attachment 2.

**UPDATE ON THE NEW
INSPECTION PROCESS:**

Caroline Juran provided the Board with a summary of all communication efforts that staff had made to provide notification to pharmacies and pharmacists of the new inspection procedures, including a newsletter article, email blast notification to all email addresses, and formal written notification to all pharmacies being inspected in the next six months of the new process and ways to prepare. In addition, she stated that forms, guidance documents, and FAQs are available on the web site explaining the new process and describing self-inspection suggestions for preparing to pass an inspection. Sammy Johnson, Deputy Director, DHP Enforcement Division, described the piloting of the new process; provided a partial sample of the inspection report being used; a sample of the summary of inspection listing whether deficiencies were found and if so, which ones; a sample of a inspection pre-hearing consent order which would be left by the inspector if warranted, and a listing of the types of deficiencies seen to date on the pilot inspections, and whether a penalty would have been imposed. Mr. Johnson stated that once we began "live" inspections using the new process in community pharmacies, the next step would be to further develop the hospital piece, particularly the requirements for USP 797. It was agreed that a committee of the Board, Mr. Ison, Ms. Abernathy, and Ms. Edwards will meet with staff to develop inspection criteria for sterile compounding compliance to be brought back to the Board at the June meeting if timelines do not change.

Board members expressed concerns about the availability of these actions on the web. Ms. Russell explained that any notice or order, of which the document imposing the monetary penalty is a consent order, is a public document and is available through license lookup. Mr. Ison expressed concern that these actions are attached to a pharmacy license and stay with that license available to the public forever. Ms. Russell stated that she is planning to look into whether these actions had to go on the Board's 90-day action list on the website, and whether there was a way to prevent this, although the documents would still be attached to the license and available to the public through license lookup or by request. She stated that she believes the 90-day action list on the website is automatically populated by the disciplinary database and there may not be an easy way to prevent these cases from being added. Mr. Ison asked

Mr. Casway to provide advice at the next Board meeting about whether a confidential consent agreement (CCA) would be an appropriate method for handling inspection deficiencies. Mr. Casway stated that he did not believe these would meet the criteria for use of a CCA. Mr. Ison asked if Mr. Casway could provide advice by the June Board meeting as to whether legislation could be developed to prevent Board actions related to inspection deficiencies from being public documents, possibly expanding the use of the CCA for this purpose. Mr. Casway stated that he could review the CCA statute, but did not expect his advice to change. Ms. Russell stated that the Board could look into a legislative proposal to further expand the use of the CCA, but did not know whether such a proposal would have support from the administration or be allowed to go forward as a Board initiative. After discussion, it was agreed that for the first six months of live inspections, the inspector would attempt to call the pharmacy alerting the PIC that an inspection would be performed at some point during the next two weeks.

PIC TRAINING:

Mr. Ison stated that he would like for the Board to offer some type of training for persons who become PIC to assist them in being able to pass a Board inspection. He added that some type of test may be appropriate. There was some discussion that a test would probably result in persons not agreeing to become a PIC, which would result in a shortage. Mr. Ison requested that a subcommittee be formed to look into appropriate training. Ms. Juran explained that all new PICs are provided with a guidance document outlining their responsibilities, and that staff will also forward a copy of the new inspection process document and how they should prepare for an inspection. Mr. Ison stated that while that was good, he did not believe that was enough and again asked the chairman to appoint a subcommittee. Ms. Edwards appointed a subcommittee of Mr. Ison, Mr. Ross, and Mr. Kozera to look into this.

**BOARD OF HEALTH
PROFESSIONS:**

Ms. Edwards stated that the BHP had not met since the previous Board of Pharmacy meeting and as such had no new report.

SUMMARY SUSPENSION:

**Motion for
closed meeting:**

The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711.A.27 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a possible summary suspension and that Scotti Russell, Cathy Reiniers-Day, Eusebia Joyner, Howard Casway, Corie Tillman Wolf and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations. (motion by Abernathy, second by Yi)

LAURA D. GOOLSBY
Pharmacy Technician
Registration Number:
0230-008314

Corie Tillman Wolf, Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

**Motion to certify the
purpose of the closed meeting:**

The Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting. (motion by Abernathy, second by Yi)

Motion:

The Board voted unanimously in favor of the motion that, according to the evidence presented, the continued practice by Laura Goolsby as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Laura Goolsby to practice as a pharmacy technician be summarily suspended and that a Consent Order be offered to Ms. Goolsby for the revocation of her registration in lieu of a hearing. (motion by Kozera; second by Beckner)

**CONFLICT OF INTEREST
TRAINING:**

The conflict of interest training program provided through the Commonwealth of Virginia's Knowledge Center was accessed and provided to the Board members as a group. All training modules were completed by the Board members. All Board members except Mr. Stredler participated in the training. Mr. Stredler completed the training online in December 2009 and provided his certificate of completion.

ADJOURN:

With all business concluded, the meeting was adjourned at 1:30PM.

Elizabeth Scott Russell
Executive Director

Jennifer Edwards, Chairman

Date

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

A hospital may use automated devices for the dispensing and administration of drugs pursuant to §54.1-3301 of the Code of Virginia and §§54.3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420 or 18VAC110-20-460 as applicable. The following conditions shall apply:

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.
2. ~~At the time of loading, the delivery record for all Schedule II through V drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.~~
3. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.
4. 3. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.
5. 4. The PIC or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:
 - a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.
 - b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.
 - c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II-V drugs administered for a time period of not less than 24 consecutive hours during the audit period.
 - d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.
 - e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.
 - f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

~~6.~~ 5. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

~~7.~~ 6. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

~~8.~~ 7. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

~~9.~~ 8. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.

~~10.~~ 9. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except:

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 10 a and b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

18VAC110-20-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

1. Pharmacist license	\$180
2. Pharmacy intern registration	\$15
3. Pharmacy technician registration	\$25
4. Pharmacy permit	\$270
5. Permitted physician licensed to dispense drugs	\$270
6. Medical equipment supplier permit	\$180
7. Humane society permit	\$20
8. Nonresident pharmacy	\$270
9. Controlled substances registrations	\$90
10. Innovative program approval.	\$250
If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	
11. Approval of a pharmacy technician training program	\$150
12. Approval of a continuing education program	\$100
13. <u>Approval of a repackaging training program</u>	<u>\$50</u>

D. Annual renewal fees.

1. Pharmacist active license	\$90
2. Pharmacist inactive license	\$45
3. Pharmacy technician registration	\$25
4. Pharmacy permit	\$270
5. Physician permit to practice pharmacy	\$270
6. Medical equipment supplier permit	\$180
7. Humane society permit	\$20
8. Nonresident pharmacy	\$270
9. Controlled substances registrations	\$90
10. Innovative program continued approval based on board order not to exceed \$200 per approval period.	
11. Approval of a pharmacy technician training program	\$75 every two years
12. <u>Approval of a repackaging training program</u>	<u>\$30 every two years</u>

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date or within two years in the case of a pharmacy technician training program. In addition, engaging in activities requiring a license, permit, or registration

after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Pharmacist license	\$30
2. Pharmacist inactive license	\$15
3. Pharmacy technician registration	\$10
4. Pharmacy permit	\$90
5. Physician permit to practice pharmacy	\$90
6. Medical equipment supplier permit	\$60
7. Humane society permit	\$5
8. Nonresident pharmacy	\$90
9. Controlled substances registrations	\$30
10. Approval of a pharmacy technician training program	\$15
<u>11. Approval of a repackaging training program</u>	<u>\$10</u>

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license	\$210
2. Pharmacist license after revocation or suspension	\$500
3. Pharmacy technician registration	\$35
4. Pharmacy technician registration after revocation or suspension	\$125
5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:	
a. Pharmacy permit	\$240
b. Physician permit to practice pharmacy	\$240
c. Medical equipment supplier permit	\$210
d. Humane society permit	\$30
e. Nonresident pharmacy	\$115
f. Controlled substances registration	\$180
g. Approval of a pharmacy technician training program	\$75
<u>h. Approval of a repackaging training program</u>	<u>\$50</u>

G. Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge	\$50
2. Change of ownership for any facility	\$50
3. Inspection for remodeling or change of location for any facility	150
4. Reinspection of any facility	\$150
5. Board-required inspection for a robotic pharmacy system	\$150

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| 6. Board-required inspection of an innovative program location | \$150 |
| 7. Change of pharmacist responsible for an approved innovative program | \$25 |

H. Miscellaneous fees.

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| 1. Duplicate wall certificate | \$25 |
| 2. Returned check | \$35 |

I. For the annual renewal due on the stated dates, the following fees shall be imposed for a license, permit or registration:

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| 1. Pharmacist active license – December 31, 2009 | \$50 |
| 2. Pharmacist inactive license – December 31, 2009 | \$25 |
| 3. Pharmacy technician registration – December 31, 2009 | \$15 |
| 4. Pharmacy permit – April 30, 2010 | \$210 |
| 5. Physician permit to practice pharmacy – February 28, 2010 | \$210 |
| 6. Medical equipment supplier permit – February 28, 2010 | \$140 |
| 7. Humane society permit – February 28, 2010 | \$20 |
| 8. Nonresident pharmacy – April 30, 2010 | \$210 |
| 9. Controlled substances registrations – February 28, 2010 | \$50 |

18VAC110-20-275. Delivery of dispensed prescriptions.

A. Pursuant to §54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver A dispensed prescription drug order for Schedule VI controlled substances prescriptions to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location unless such delivery is authorized by federal law and regulations of the board.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.
2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:
 - a. A description of how each pharmacy will comply with all applicable federal and state law;
 - b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its

assigned responsibilities, method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;

c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and

h. The procedure for informing the patient and obtaining consent for using such a dispensing and delivery process.

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.

2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:

a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;

b. Procedure for providing counseling;

c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;

d. The procedure for assuring confidentiality of patient information; and

e. The procedure for informing the patient and obtaining consent for using such a delivery process.

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, ~~or either person's designee or other person as authorized in 18VAC110-20-700 C.~~

D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.

E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably assured.

Part XVI. Controlled Substances Registration for Other Persons or Entities

18VAC110-20-685. Definitions.

For purposes of this part, the following definitions shall apply.

"CSB" means a community services board facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the Board.

"BHA" means a behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the Board.

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

A. A person or entity which maintains or intends to maintain a supply of Schedule II through Schedule VI controlled substances, other than manufacturers' samples, in accordance with provisions of the Drug Control Act (§54.1-3400 et seq. of the Code of Virginia) may apply for a controlled substances registration on forms approved by the board.

B. Persons or entities which may be registered by the board shall include, but not be limited to, hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternative delivery sites, crisis stabilization units, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

C. In determining whether to register an applicant, the board shall consider factors listed in subsections A and D of §54.1-3423 of the Code of Virginia and compliance with applicable requirements of this chapter.

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.

2. Controlled substances registration applications that indicate a requested inspection date, or requests that are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

3. Requested inspection dates that do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

4. Any person wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall file an application with the board and be inspected consistent with subsection B of this section.

5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, or pharmacy technician for alternate delivery sites, or other person approved by the board who is authorized to administer ~~or otherwise possess the controlled substances for that type entity.~~

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedule II through VI controlled substances have been obtained and are being used as common stock by multiple practitioners and that one or more of the following factors exist:

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.
2. The person or entity has experienced a diversion, theft, or other unusual loss of controlled substances which requires reporting pursuant to §54.1-3404 of the Drug Control Act.
3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.
4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.
2. In an emergency medical services agency, the operational medical director shall supervise.
3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs which may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia, or to such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB or BHA as authorized in § 54.1-3420.2, or to other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation. If approved by the supervising practitioner, pharmacy technicians may have access for the

purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, ~~and~~ overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB or BHA as authorized in § 54.1-3420.2. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including, but not limited to, storage, security, and recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

18VAC110-20-725. Repackaging by a CSB or BHA.

A. Definition.

For purposes of this section, "repackaging" shall mean removing a drug from a container already dispensed and labeled by a pharmacy or medical practitioner authorized to dispense, for a particular client of a CSB or BHA, and placing it in a container that is designed for a person to be able to repack his own dispensed prescription medications to assist with self-administration and compliance with dosage instructions. Such repackaging shall not include the preparation of a patient-specific label which includes drug name, strength, or directions for use or any other process restricted to a pharmacist or pharmacy technician under the direct supervision of a pharmacist.

B. Persons authorized to repack.

Repackaging shall be performed by a pharmacist, pharmacy technician, nurse, or such other person who has successfully completed a board-approved training program for repackaging of prescription drug orders as authorized in § 54.1-3420.2. A CSB or BHA using such other persons shall maintain documentation of completion of an approved training program for at least one year from date of termination of employment or cessation of repackaging activities.

C. Requirements for repackaging.

1. The repackaging of a dispensed prescription drug order pursuant to § 54.1-3420.2 shall only be done at a CSB or BHA.

2. The repackaging of dispensed prescription drugs shall be restricted to solid oral dosage forms and a maximum of a 14-day supply of drugs.

3. The drug container used for repackaging pursuant to this section shall bear a label containing the client's first and last name, and name and 24-hour contact information for the CSB or BHA.

4. A clean, well-closed container that assists the client with self-administration shall be used when multiple doses of a repackaged drug are provided to the client at one time.

5. A prescription drug order shall not be repackaged beyond the assigned expiration date noted on the prescription label of the dispensed drug, if applicable, or beyond one year from the date the drug was originally dispensed by a pharmacy, whichever date is earlier.

D. Written information for client.

At the time a repackaged drug is initially given to a client, and upon any subsequent change in the medication order, the client shall be provided written information about the name and strength of the drug and the directions for use. Such written information shall have been prepared by a pharmacy or by a nurse at the CSB or BHA.

E. Retention, storage and destruction of repackaged drugs.

1. Any portion of a client's prescription drug order not placed into a container intended to assist with self-administration may be either given to the client or retained by the CSB or BHA for subsequent repackaging. If retained by the CSB or BHA, the remaining portion shall be stored within the board-approved drug storage location in the original labeled container, and shall only be used for the client for whom the drug was originally dispensed.

2. Any portion of a prescription drug order remaining at the CSB or BHA that has exceeded any labeled expiration date or one year from the original pharmacy dispensing date on the label shall be separated from unexpired drugs, stored within a designated area of the board-approved drug storage location, and destroyed within 30 days of expiration with the written agreement of the client. Remaining portions of discontinued prescription drug orders retained by the CSB or BHA shall also be separated from active stock and either returned to the client or destroyed within 30 days of discontinuance with the written agreement of the client.

F. Recordkeeping.

1. A record of repackaging shall be made and maintained for one year from the date of repackaging and shall include the following:

a. Date of repackaging;

b. Name of client;

c. Prescription number of the originally dispensed prescription drug order;

d. Pharmacy name;

e. Drug name and strength;

f. Quantity of drug repackaged; and

g. Initials of the person performing the repackaging and verifying the accuracy of the repackaged drug container.

2. A record of destruction shall be made and maintained for one year for any prescription drug orders destroyed by the CSB or BHA and shall include the following:

a. Date of destruction;

b. Name of client;

c. Prescription number of the originally dispensed prescription drug order;

d. Drug name and strength;

e. Quantity of drug destroyed; and

f. Initials of the person performing the destruction.

18VAC110-20-726. Criteria for approval of repackaging training programs.

A. Application.

Any person wishing to apply for approval of a repackaging training program shall submit the application fee prescribed in 18VAC110-20-20 and an application on a form approved by the board and shall meet the criteria established in this section. The application shall name a program director who is responsible for compliance with this section.

B. Curriculum.

The curriculum for a repackaging training program shall include instruction in current laws and regulations applicable to a CSB or BHA for the purpose of assisting a client with self-administration pursuant to §54.1-3420.2, and in the following repackaging tasks:

a. Selection of an appropriate container;

b. Proper preparation of a container in accordance with instructions for administration;

c. Selection of the drug;

d. Counting of the drug;

e. Repackaging of the drug within the selected container;

f. Maintenance of records;

g. Proper storage of drugs;

h. Translation of medical abbreviations;

i. Review of administration records and prescriber's orders for the purpose of identifying any changes in dosage administration;

j. Reporting and recording the client's failure to take medication;

k. Identification, separation and removal of expired or discontinued drugs; and

l. Prevention and reporting of repackaging errors.

C. Instructors and program director.

Instructors for the program shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any jurisdiction in the United States; or (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked in any jurisdiction in the United States. The program director shall maintain a list of instructors for the program.

D. Program requirements.

1. The length of the program shall be sufficient to prepare a program participant to competently perform repackaging consistent with §54.1-3420.2 and 18 VAC 110-20-725.
2. The program shall include a post-training assessment to demonstrate the knowledge and skills necessary for repackaging with safety and accuracy.
3. A program shall provide a certificate of completion to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by a CSB or BHA or by the board.
4. The program shall maintain records of training completion by persons authorized to repackage in accordance with §54.1-3420.2. Records shall be retained for two years from date of completion of training or termination of the program.
5. The program shall report within 14 days any substantive change in the program to include a change in program name, program director, name of institution or business if applicable, address, program content, length of program, or location of records.

E. Expiration and renewal of program approval.

A repackaging training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a self-evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.

18VAC110-20-727. Pharmacists repackaging for clients of a CSB or BHA

As an alternative to repackaging as defined in 18 VAC 110-20-725, a pharmacist at a CSB or BHA may repackage a client's prescription drugs that have been dispensed by another pharmacy into compliance packaging that complies with the requirements of 18 VAC 110-20-340 B and 18 VAC 110-20-725, subsections G, H, and J. A primary provider pharmacy may also provide this service in compliance with the provisions of 18 VAC 110-20-535.

18VAC110-20-728. Drugs for immediate treatment in crisis stabilization units.

A. In accordance with § 54.1-3423, a crisis stabilization unit shall apply and obtain a controlled substances registration in order to maintain a stock of Schedule VI controlled substances for immediate treatment of patients in crisis. Schedule II-V controlled substances shall not be stocked. The responsible party listed on the application shall be a nurse who regularly administers controlled substances at the crisis stabilization unit and the supervising practitioner shall be either the medical director for the unit or a pharmacist from a provider pharmacy.

B. In consultation with a provider pharmacist, the medical director for the unit shall determine the list of controlled substances to be stocked at the crisis stabilization unit. The list shall be limited to Schedule VI controlled substances and only those drugs routinely used for treatment of patients admitted for crisis stabilization. Only drugs on this drug list may be stocked.

C. A nurse administering a drug from this stock pursuant to an oral order of a prescriber in accordance with § 54.1-3423, shall record such order in the patient's medical record.

D. Records.

1. A record shall be maintained of all drugs received as stock by the crisis stabilization unit.
2. A record shall be made documenting administration or other authorized disposition of stocked drugs that includes the following:
 - a. Name of patient;
 - b. Date and time of administration;
 - c. Drug name, strength, and quantity administered;
 - d. Name or initials of person administering; and
 - e. Prescriber name.
3. Records shall be maintained at the same location listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It shall also have the capacity of producing a printout of any data which the registrant is responsible for maintaining.
4. Manual records may be maintained as an electronic image that provides an exact image of the document and is clearly legible.